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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,097	06/14/2001	Anton Wellstein	102728-P01-004	3830

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EXAMINER

KOLKER, DANIEL E

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/880,097		WELLSTEIN, ANTON	
	<b>Examiner</b>		<b>Art Unit</b>	
	Daniel Kolker		1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 95-118 is/are pending in the application.
- 4a) Of the above claim(s) 106-118 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 95-118 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

1. Applicant's remarks and amendments filed 6 December 2005 have been entered. Claims 95 – 118 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

### ***Election/Restrictions***

4. Claims 106 – 118 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2 February 2004.
5. This application contains claims 106 – 118 are drawn to an invention nonelected with traverse in the remarks filed 2 February 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Withdrawn Rejections and Objections***

6. The following rejections and objections made in the previous office action are withdrawn:
  - 1) The objection to the Information Disclosure Statement is withdrawn; the search report is in proper format for publication on the face of a patent.
  - 2) The rejection of claim 103 under 35 USC 112, second paragraph is withdrawn in light of applicant's argument.

### ***Rejections and Objections Maintained***

#### ***Claim Rejections - 35 USC § 112***

7. Claims 95 – 105 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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This rejection is maintained for the reasons set forth previously. Applicant argues that the amendment of claim 95 to recite "human pleiotrophin" is sufficient to overcome the rejection. Applicant argues that "human" is a functional characteristic of the pleiotrophin to which the claimed protein binds. Applicant's arguments have been fully considered but they are not persuasive. First, the limitation "human" is not a functional characteristic of the PTN protein. By limiting the claim to a protein which binds to human PTN applicant has limited the scope of the claim, but not limited the function of the claimed polypeptides. Additionally, this limitation fails to overcome the rejection set forth in the previous office action. PTN is not defined explicitly in the specification, and the art recognizes that molecules anywhere between 40 and 168 amino acids long are PTN. There is no requirement that the claimed proteins bind to any particular part of PTN. A skilled artisan would have to resort to undue experimentation to test whether the claimed polypeptides bind to the broad genus of molecules called pleiotrophin.

8. Claims 95 – 105 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

This rejection is maintained for the reasons set forth in the previous office action. Applicant argues that the amendment of claim 95 to recite "human pleiotrophin" is sufficient to overcome the rejection. Applicant argues that "human" is a functional characteristic of the pleiotrophin to which the claimed protein binds. Applicant's arguments have been fully considered but they are not persuasive.

Limiting the PTN molecule to which the claimed polypeptides bind to human fails to overcome the rejection. The examiner set forth in the previous office action that there was not sufficient evidence to conclude that the claimed molecules bind to the entire genus of PTN. PTN is very broad and not well-defined in the art. As set forth previously, molecules that are 40 and 168 amino acids long are both called PTN. The claims, as amended, do not convey to one skilled in the art that applicant possessed a reasonable number of members of the broad genus claimed. Pleiotrophin, as defined in the art, clearly includes both the 40-residue peptide and the 168-residue peptide. The specification does not provide support for the entire genus.

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9. Claims 95 – 105 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended claim 95 to recite “as encoded by GenBank accession number U66559”. This is sufficient to overcome the rejection, but only to the extent that the claim was unclear because it claimed a protein that had a nucleic acid sequence. Claim 95 remains vague and indefinite because it is unclear whether positions 368 – 447 refer to residues in the sequence of the claimed polypeptide, or to residues in the protein encoded by U66559. Furthermore, it is unclear whether the residue numbers recited in the claim refer to residues of a full-length protein or of a mature protein, i.e. without the signal sequence. Given the multiple ways that the claim could be interpreted, the skilled artisan could not determine the metes and bounds of claim 95.

Applicant argues that the metes and bounds of claim 105 do not relate to the test substance, but rather to the polypeptide that is also a component of the composition. Applicant’s arguments have been fully considered but are not persuasive. Claim 105 clearly comprises at least three elements:

- 1) a polypeptide of claim 95, 97, or 98
- 2) PTN
- 3) a test substance

The claim is evaluated under 112, second paragraph, not for whether or not a single element of the composition is indefinite, but rather whether the skilled artisan could determine the metes and bounds of the claim. Thus consideration of whether or not “test substance” is indefinite is entirely appropriate. This term could be anything, as any substance could be tested. The preamble of the claim is not drawn to testing, and it is unclear and confusing as to what is being tested. A skilled artisan could not determine the metes and bounds of this claim, because it is unclear what substances, molecules, or compositions of matter constitute “a test substance”.

Claims 96 – 104 are rejected because they depend from a rejected base or intermediate claim.

#### ***Claim Rejections - 35 USC § 102***

10. Claims 95 – 99, 101, and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Aigner (March 1999, Proceedings of AACR, of record).

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This rejection is maintained for the reasons set forth previously and explained in further detail below. In the previous office action, the examiner set forth a *prima facie* case that Aigner anticipates the claimed invention. Briefly, Aigner et al. teach a polypeptide that binds to PTN; the instant inventor is an author on the Aigner reference, and the reference used the same technique and starting materials to isolate the protein. The reference teaches the claimed product. Whether or not it teaches all inherent properties, such as amino acid sequences, is irrelevant, as a product and its inherent properties are inseparable.

Applicant argues that since other molecules bind to PTN, the rejection is not proper as the reference does not disclose the inherent properties of the molecule. Applicant's arguments have been fully considered but are not persuasive. The examiner set forth a *prima facie* case that Aigner anticipates the claimed invention. Once such a case has been set forth, the burden shifts to the applicant to distinguish the claimed invention over the prior art. See MPEP § 2112(V). In this case, applicant has failed to show how the claimed invention is different from the prior art product and thus the rejection is maintained.

11. Claims 95 – 98 are rejected under 35 U.S.C. 102(b) as being anticipated by Morris (U.S. Patent 5,770,421, of record).

This rejection is maintained for the reasons set forth previously and explained below. Morris teaches that the extracellular domain of human ALK comprises the first 1030 residues of the peptide, including the signal sequence (see column 26 lines 62 – 66). Applicant argues that since the signal sequence is cleaved during cellular processing, the extracellular domain does not include residues 1 – 26, and thus claim 5 from Morris actually includes the entire extracellular domain. Applicant's arguments have been fully considered but are not persuasive. Applicant has not explicitly defined "the extracellular domain" of the protein and thus the examiner must rely on the prior art definition. Morris defines the extracellular domain as including the signal sequence. Morris also teaches a protein comprising a portion of, but not the entire, extracellular domain (see claim 5 from Morris). Thus Morris teaches the claimed invention.

### ***Rejections and Objections Necessitated by Amendment***

#### ***Claim Objections***

12. Applicant is advised that should claim 96 be found allowable, claim 97 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application

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are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The listing of the claims filed 6 December 2005 indicates that claim 96 was previously presented. However, the version of claim 96 presented previously (16 March 2005) was drawn to a polypeptide lacking tyrosine kinase activity.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Daniel E. Kolker, Ph.D.

January 5, 2006



SHARON TURNER, PH.D.

PRIMARY EXAMINER

1-10-06